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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/648,306 | 08/25/2000 | Cameron J. Koch | UPN-3904 | 6906 |

7590

09/05/2002

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| EXAMINER |
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WRIGHT, SONYA N

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| ART UNIT | PAPER NUMBER |
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1626

DATE MAILED: 09/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/648,306

Applicant(s)

KOCH ET AL.

Examiner

Sonya Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-22 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 20-22 and 27-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

This Office Action is in response to Applicant's Amendment and Request for Reconsideration filed 7-3-02. Claims 20 and 28-32 have been amended. Claims 20-22 and 28-32 are pending in this application.

The double patenting rejection has been overcome with Applicant's amendment. The rejection under 35 U.S.C. 103 has been maintained for the reasons set forth in the Office Action mailed 4-4-02. The rejection under 35 U.S.C. 112 has been overcome with Applicant's amendment.

Claim Rejections - 35 USC § 103

Claims 20-22 and 27-32 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over US Patent 5,540,908, which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the application, it constitutes prior art under 35 U.S.C. 102(e).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 20-22 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,540,908, Koch et al..

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim a method for detecting tissue hypoxia in a mammal, and Koch et al. teach a method for detecting tissue hypoxia in a mammal. Koch et al. teach instant claims 20, -22 and 27-32 in column 1, lines 24-26, and column 6, lines 10-26. (Also see column 7, lines 20-29, for instant claims 20 and 21). Koch et al. teach the instant claims, when, in the instant claims, R₁ and R₂ are as defined.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art and the instant claims is that in Koch et al., claim 14, in variable R₂, Y is fluorine, therefore, the terminal carbon in R₂ must have three fluorine atoms. In the instant claims, the terminal carbon in the R₂ substituent can have at the most two carbons. Further, in the instant claims, there must be at least one F18 atom in the R₂ variable. In Koch et al., X is halogen and Y is fluorine, however, Koch et al. do not specify that an F18 atom must be present in variable R₂. However, Koch et al. generically teach the presence of an F18 atom in R₂ by defining X as halogen and by defining Y as fluorine.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

One of ordinary skill in the art would be motivated to use the teachings of Koch et al. to use the instant compounds in detecting tissue hypoxia in the expectation that all compounds under the genus would have similar methods of use.

The compounds of Koch et al. require three fluorine atoms at the terminal carbon of variable R₂, while in the instant claims, the terminal carbon can have at the most, two fluorine atoms. Therefore, the instant claims are homologs of the compounds of Koch

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et al. To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare homologs of the compounds taught in the reference with the expectation of obtaining compounds which could be used in positron emission tomography. Therefore, the instant claimed compounds would have been suggested to one skilled in the art. Koch et al. gives guidance to prepare the instant compounds in column 6, line 23, wherein the preferred halogen atom is fluorine. Further, see column 14, lines 23-24, which states that using PET the preferred isotope is F^{18} .

Response to Arguments

Applicant's arguments filed 7-3-02 have been fully considered but they are not persuasive with respect to the rejection under 35 U.S.C. 103. In the last office action from the Examiner, the Examiner stated that if the rejections under 35 U.S.C. 112 first and second paragraphs are overcome, the obviousness double patenting rejection and the rejection under 35 U.S.C. 103 will also be overcome. Applicant has overcome the rejections under 35 U.S.C. 112 first and second paragraphs, and the obviousness type double patenting rejection has been overcome, but after consideration of Applicant's amendment, the rejection under 35 U.S.C. 103 has been maintained.

The difference between the prior art and the instant claims is that in Koch et al., claim 14, in variable R2, Y is fluorine, therefore, the terminal carbon in R2 must have

three fluorine atoms. In the instant claims, the terminal carbon in the R2 substituent can have at the most two carbons. Further, in the instant claims, there must be at least one F18 atom in the R2 variable. In Koch et al., X is halogen and Y is fluorine, however, Koch et al. do not specify that an F18 atom must be present in variable R2. However, Koch et al. generically teach the presence of an F18 atom in R2 by defining X as halogen and by defining Y as fluorine.

One of ordinary skill in the art would be motivated to use the teachings of Koch et al. to use the instant compounds in detecting tissue hypoxia in the expectation that all compounds under the genus would have similar methods of use.

The compounds of Koch et al. require three fluorine atoms at the terminal carbon of variable R2, while in the instant claims, the terminal carbon can have at the most, two fluorine atoms. Therefore, the instant claims are homologs of the compounds of Koch et al. To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare homologs of the compounds taught in the reference with the expectation of obtaining compounds which could be used in positron emission tomography. Therefore, the instant claimed compounds would have been suggested to one skilled in the art. Koch et al. gives guidance to prepare the instant compounds in column 6, line 23, wherein the preferred halogen atom is fluorine. Further, see column 14, lines 23-24, which states that using PET the preferred isotope is F18.

It has been noted in this office action that the compounds of Koch et al. and the compounds in the instant claims differ by the R2 variable. It is suggested that Applicant show unexpected results with the instant invention in order to overcome the rejection under 35 U.S.C. 103.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.



Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

August 29, 2002